IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

OIPE IAP13 AUG 09 2006 PATENT & TRADEMARK OFFICE

In re Patent Application of
John O'Mahony et al.
Serial No. 10/601,574
Filed: June 24, 2003

Atty. Ref.: 3659-67
TC/A.U.: 3761
Examiner: DEAK, Leslie R.

For: METHOD AND APPARATUS FOR BLOOD WITHDRAWAL AND INFUSION USING A PRESSURE CONTROLLER

* *

August 9, 2006

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

In response to the Examiner's Answer of June 9, 2006, Applicant submits this Reply brief.

The sole remaining issue in this appeal is: "[w]hether claims 82 to 85 are anticipated under 35 U.S.C. §102(b) by Kenley et al (US Patent 5,690,831)."

There is no anticipation because Kenley et al do not disclose several features of claims 82 to 85 including:

- A pump actuator having ... a second configuration in which a negative pressure in the return line, whereby a flow through said return line may be reversed ... (Claim 82). The return line 492 in Kenley et al is never under a negative pressure and is clamped shut when the blood pump is reversed.

Contrary to the Action, the blood line 470 in Kenley et al is not a "return line" as called for in claim 82 because it is not connected to a patient access.

- A pump actuator in the second configuration configured to reverse a flow in both said return line and said draw line. (Claims 83 and 85). The reversing pump in Kenley et al does not reverse blood flow in return line 492.
- A pump actuator having a reverse flow operational mode in which the actuator generates a negative pressure in fluid line and a flow through said return line is reversed. (Claim 84). Kenley et al do not teach a reverse blood flow through return line 492.

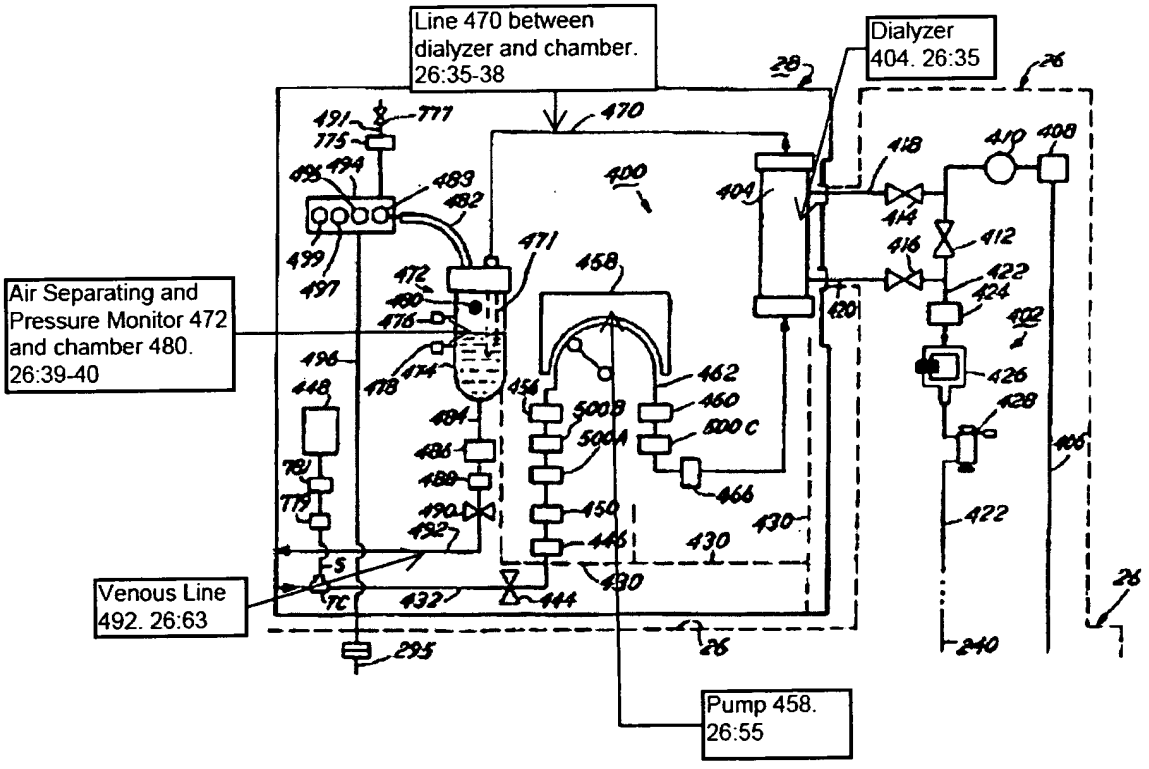
A. Line 470 In Kenley et al Is Not A Return Line Connectable to Patient Access

The return line in claim 82 is "connectable to said at least one patient access." A patient access is a line or device that access the patient, such as a catheter inserted into a vein of the patient. *See* Spec. p. 16, lns. 19-25; p. 46, first paragraph. In Kenley at al, the return line is line 492 that is the "venous line 492 which leads to the patient." Kenley, col. 26, lns. 63-64.

The return line in the blood circuit shown in Figure 13 of Kenley et al is venous line 492. Kenley et al, col. 26, lns. 60-64 ("The bottom of the chamber 474 is connected to a line 484 having an ultrasonic air bubble detector 486, a blood sensor 488 and a clamp 490 and is connected to **the venous line 492 which leads to the patient**." (emphasis added)). The return line 492 in Kenley et al allows blood to flow from the bottom of the air separator 472 to the patient.

Contrary to the Action, the line 470 is not a return line that is connectable to a patient access. The Kenley blood line 470 has an outlet connected to an air separator 472 and an inlet connected to a dialyzer. Kenley, col. 26, lns. 35-38 ("The blood is returned to the patient via line 470 to an air-separating and pressure monitoring chamber 472 having an inlet tube 471 at the top or bottom, with the top preferred."). The air separator and dialyzer are not patient access devices.

The figure below is an annotated Figure 13 from Kenley et al and shows that the blood line 470 is not connected to a patient access.[1]



The blood line 470 is separated by air separator 472 from the return line 492 which is connected to a patient access. The separator removes air in the blood line 470.

Air bubbles may occur in the blood line 470. As blood flows from the outlet of line 740 in enters the chamber 480 of the separator 472. Air in the blood bubbles to the top of the chamber and is vented. Blood settles in the chamber and ultimately drains out of the chamber bottom and into return line 492.

To connect blood line 470 to a "patient access" device (rather than the separator) would endanger the patient. Blood line 470 may contain air. To connect the blood line 470 to a patient access device could introduce an air bubble in the venous system of the patient. Air in the venous system is dangerous and is to be avoided. A person of ordinary skill in the art would not read Kenley et al as teaching coupling blood line 470 to a patient access device.

The Kenley blood line 470 is not in fluid communication with a patient access. When the pump is reversed, the blood line 492 is clamped shut to ensure that no blood is drawn out of the patient through the return line 492. Kenley, col. 26, lns. 57-60. The clamp prevents fluid flow through the return line 492 while the pump is reversed. Accordingly, the blood line 470 is not in fluid communication with the return line (or a patient access) when the blood pump is reversed.

B. Air Separator 472 In Kenley et al Cannot Apply Negative Pressure To Return Line 492

The blood return line 492 in Kenley et al is not subjected to a negative pressure. A reversing blood pump may form a negative pressure in the blood line 470, but will not form a negative pressure in the return line 492. The air separator 472 in Kenley et al has a chamber 480 with an upper region open to the atmosphere and is under a positive

[1] In the above figure, the references to the column and lines of Kenley et al are indicated in the text boxes.

pressure to induce blood into the return line 492 and into the venous system of the patient. Kenley, col. 26, lns. 50-58 ("... the fluid in the chamber 474 is normally under positive pressure during dialysis ....). Reversing the Kenley blood pump may lower the blood level in chamber 472, but will not create a negative pressure in blood line 492.

Dropping the blood level in the chamber 472 does not create a negative pressure in the chamber or in line 492. The pump is operated in reverse only until the blood level in the chamber drops to the level of a sensor 478. Henley, col. 26, ln. 59-60. The positive pressure in the chamber 472, the clamp on line 492, and the sensor 478 that stops the reversing blood pump if the chamber levels drops too low ensure that there is never a negative pressure in line 492.

C. The Kenley Air Separator Chamber Is Not Operated With A Negative Pressure

Kenley et al do not disclose a negative pressure in the air separation chamber. The chamber is under a positive pressure when the blood pump 458 is reversed because it is reversed at ½ the rate of the dialysis pump. Thus the pressure in the air separation chamber 471 is still positive because the other ½ of the dialysis flow is being through it back to the patient.

If we consider what will happened with the air separation chamber if it were to experience negative pressure we will understand that the design as currently described has no way to accommodate negative pressures. Under positive pressure, expanding gas is relieved to atmospheric pressure via the vent valve at 777. Given that gas expands

under reducing / negative pressure like a divers bubble rising to the surface. Thus if the blood pump were to reverse and cause a negative pressure in the air separation chamber gas would expand. In this case the venting of gas via 777 to prevent the liquid with the air separation chamber from passing the sensor 478 would have the opposite effect of entraining further air and accelerating the infusion of air into the patient. It would be necessary to have a vacuum attached to the vent valve 777 to prevent the gas from expanding by opening valve 777.

This Kenley does not describe a system that facilitates the reversals of pump without causing the infusion of air to the patient when the entrained gas within the air separation chamber is exposed to negative pressure.

D. Rejected Claims Were Copied To Provoke Interference With An Issued Patent

Applicants have copied claims to provoke an interference with US Patent 6,572,576 ('576 Patent). In particular, claims 54 and 55 of the '576 Patent were substantively copied to this application as claims 59 and 60. and are similar in most respects to pending claims 82 to 85. Claims 59 and 60 were canceled from this application due to 112 rejections that are equally applicable to claims 54 and 55 in the '576 Patent. Claims 82 to 85 overcome the 112 rejections, and are similar to claims 54 and 55 that have been allowed by the PTO and are in the issued '576 Patent.

Consistency of standards on anticipation as applied by the USPTO during examination should not result in claims being rejected for anticipation in one application

and allowed in another. The rejected are substantively similar to claims 54 and 55 in US Patent 6,572,576 ('576 Patent). Kenley et al is identified on the face of the '576 Patent as a considered reference. The examiner for the '576 Patent apparently viewed claims 54 and 55 of that patent to be allowable over Kenley et al. Allowing the rejected claims of this application would consistent with the allowance of claims 54 and 55 in the '576 Patent. The allowance of the rejected claims would allow this application to proceed to an interference with the '576 Patent.[2]

CONCLUSION

In conclusion it is believed that the application is in clear condition for allowance; therefore, early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

Reg No 50,964

By: Gordon Kit for
Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

[2] Claims 54 and 55 of the '576 Patent are subject to the same infirmities for which cancelled claims 59 and 60 were rejected. In particular, claims 54 and 55 of the '576 Patent and cancelled claims 59 and 60 are directed to a leak detector but do not recite any detection element. Cancelled claims 59 and 60 were rejected for not claiming "essential elements".